

REMARKS/ARGUMENTS

In the Office Action issued March 29, 2004, all pending claims 14-17 and 19-29 were rejected. In response thereto, claims 23 and 29 have been cancelled, claims 14, 15, 19, 21, 22, 24, 25, 27, and 28 have been amended, and new claims 30-91 have been added. More specifically, claim 14 has been amended to replace the term "liquid" with "platelet rich plasma" and to clarify that the restoration agent and an activation agent are positioned within the first vessel in amounts sufficient to allow formation of a clot upon receiving the platelet rich plasma. Support for this amendment can be found on page 76, lines 16-24 and 77, lines 11-12. Independent claim 22 has been amended to replace the term "liquid" with "platelet rich plasma" and to further recite that the first vessel contains a restoration agent and an activation agent in amounts sufficient to allow formation of a clot. Claim 22 has also been amended to clarify that the lumen assembly is configured to provide the platelet rich plasma concurrently or selectively to the two vessels. Dependent claim 25 has been amended to recite that the filter element comprises glass wool, which also serves as the activation agent. Support for this amendment can be found on page 77, lines 13-16. New claims 30-91 have been added to provide protection of another embodiment of a platelet gel dispenser and a platelet gel system not shown or suggested by the cited references.

No new matter is added by these amendments, and claims 14-17, 19-22, 24-28, and 30-91 remain for consideration by the Examiner.

A. Claim Rejections Under 35 U.S.C. §112

In the Office Action of March 29, 2004, claim 22 was rejected as being indefinite because it was not clear whether the filter and activating agent were two components or one. Claim 22 has amended to clarify that the first vessel contains a restoration, an activation agent, and a filter element. As described on page 76, line 17 through page 77, line 18, the filter can be the same as or different than the activation agent. Claim 25 has been amended to further recite that filter element can be glass wool, which can also serve as the activation agent. It is asserted that claim 22 as amended herein is clear and definite, and withdrawal of this rejection is respectfully requested.

B. Claim Rejections Under 35 U.S.C. §102

1. The Office Action rejected claims 14-17, 19-21, and 29 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,274,090 (“Coelho”). This rejection is traversed based on the following remarks.

Claim 29 has been cancelled herein. Claim 14 is directed toward a platelet gel dispenser with first and second vessels. A restoration agent and an activation agent are included in the chamber of the first vessel and are “positioned within the chamber prior to receiving the platelet rich plasma.” Because each of these elements is not shown by Coelho, the rejection of claim 14 under 102(e) is improper and should be withdrawn. Further, the Examiner cites Figures 1-4 and the “entire reference” of Coelho for teaching a dispenser with two chambers and a restoration agent of calcium and an activating agent that is a chemical agent. However, the Examiner does not point to any particular citation in Coelho that teaches a restoration agent and an activation agent within the first chamber before the platelet rich plasma is received therein.

It is asserted that Coelho teaches away from the dispenser of claim 14 by teaching that the restoration agent and the activating agent are stored in separate vials outside of the chamber that holds plasma. The vials are broken after plasma is drawn into a chamber, and then the reagents are individually or separately drawn into the chamber. In Figures 1-4, Coelho shows reagent ampoules 32, 34 that are separate and distinct from mixing syringe 26. Per Coelho at col. 5, lines 50 to col. 6, line 30, the valve 24 is oriented first to draw plasma into the mixing syringe 26, and then reoriented “so that access can be gained between the mixing syringe 26 and the reagents found in ampoules 32, 34” which have to be squeezed to rupture a diaphragm. Hence, Coelho teaches against placing the restoration agent and the activation agent within the syringe 26 prior to receiving the plasma sample. For at least this reason, claim 14 is not anticipated or even suggested by Coelho and is believed in condition for allowance. Claims 15, 16, and 19-21 depend from claim 14 and are believed allowable as depending from an allowable base claim.

2. Claims 22, 23, and 26 were rejected under 102(e) as being anticipated by U.S. Pat. No. 6,159,232 (“Nowakowski”). This rejection is traversed based on the amendments to independent claim 22 and the following remarks.

Claim 23 has been cancelled herein. Claim 22 is directed to a platelet gel dispenser that includes a first vessel for storing a first volume of platelet rich plasma and a second

vessel for storing a second volume of platelet rich plasma. In addition, a restoration agent and an activation agent are disposed within the first vessel in an amount sufficient to form a clot after the first volume of platelet rich plasma is drawn into the first vessel. A lumen assembly is provided that is configured to provide the platelet rich plasma concurrently or selectively to the two vessels. In other words, the platelet rich plasma is not processed through the first vessel prior storing in the second vessel. The dispenser further includes a filter element positioned within the first vessel that is configured for filtering thrombin from the clot. Nowakowski fails to show each element of the claimed dispenser, and therefore the rejection of claim 22 is improper and should be withdrawn.

Specifically, the Office Action cites Nowakowski at Figures 1-4 and the “entire reference” for teaching a lumen connecting two vessels (elements 1 and 9 in the figures) and a restoration agent and an activating agent. Instead, Nowakowski teaches that anticoagulated blood is first drawn through filters 13, 14, and 15, each of which is disposed outside of the chamber. The filter 15, which contains DEAE to bind the anticoagulant (i.e., heparin) in the blood, also acts as a procoagulant to initiate clotting. The blood which is activated outside of the chamber is then drawn into chamber 1. Further, as can be seen in Figures 2-4, Nowakowski fails to teach the lumen assembly of claim 22. Hence, there is no lumen assembly that can distribute the blood from assembly 29 concurrently or selectively to the chambers 1 and 9, as called for in claim 22. In addition, Nowakowski fails to teach a filter positioned within the chamber for filtering thrombin from a clot, wherein the clot is formed within the chamber. In fact, Nowakowski teaches that the activated blood fluid is delivered back to the patient prior to the formation of a clot. Nowakowski fails to teach the formation of a clot within a chamber outside of the patient. For at least the above reasons, Nowakowski fails to anticipate the dispenser of claim 22.

Claim 26 depends from claim 22 and is believed allowable for the reasons for allowing claim 22.

C. Rejections Under 35 U.S.C. § 103

1. In the Office Action, claims 14-17, 19-24, and 26-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 5,887,755 (“Hood”) in view of U.S. Pat. No. 6,482,223 (“Nowakowski et al.”). This rejection is traversed based on the following remarks.

Claims 23 and 29 have been cancelled herein. As discussed with reference to claim 22 above, Hood also fails to teach a lumen assembly for providing a single liquid concurrently or selectively in a dispenser. Instead, Hood in Figure 1 and elsewhere teaches two chambers or syringes 102, 104 whose outputs can be mixed in chamber 116. There is no teaching of a lumen assembly configured for concurrently or selectively providing a single liquid to both syringes 102, 104. The Nowakowski et al. system shown in Figure 1 and elsewhere is similar to systems cited in Nowakowski, cited in the Office Action as a 102 reference, and hence, fails to include the claimed lumen assembly. For this reason, claim 22 and claims 24 and 26-28 which depend from claim 22 are allowable over this combination of references.

Further, neither reference teaches placing an activating agent within a first chamber. The Office Action cites Nowakowski et al. for teaching such an activator, however, as discussed above Nowakowski teaches an activator (filter 15) disposed outside of the chamber. That is, the Nowakowski apparatus activates the blood before it enters the chamber. Additionally, claims 14 and 23 call for both a restoration agent and an activating agent disposed within the chamber, while the cited references do not show the use of both elements in a single chamber. Further, claim 14 calls for the restoration agent and activator to be placed within the same chamber before the anticoagulated blood is received therein. Hence, claims 14 and 22 and claims 15-17, 19-21, and 24-28 which depend from these two independent claims are allowable over the combined teaching of these references.

The Office Action again has cited the “entire reference” when citing Hood for teaching a restoration agent that is calcium. For the Office Action to satisfy the requirements of 103, the MPEP requires that the Office provide specific citations in a reference to where each and every element is taught or suggested. Should the Office decide not to allow this case, Applicants request clarification as to where Hood teaches the positioning of a restoration agent in a chamber that also includes an activation agent as is required by claims 14 and 23. Because Hood does not overcome the deficiencies of Nowakowski et al. and because there is no motivation in Hood to modify it with the teachings of Nowakowski, claims 14-17, 19-22, 24, and 26-28 are allowable over these references.

Further, even if Hood and Nowakowski et al. were combined, the dispenser of claims 14 and 22 would not be achieved because there would be no activating agent. Significantly, Nowakowski et al. is mainly aimed at removing heparin from a patient’s blood which is only part of the problem addressed by Applicants’ claimed dispensers.

2. Claims 14-17 and 19-29 were rejected under 35 U.S.C. §103(a) as being unpatentable based on the combination of Hood and Nowakowski et al. and further in view of U.S. Pat. No. 5,795,780 ("Cederholm-Williams"). This rejection is traversed based on the following remarks.

Cederholm-Williams does not overcome the deficiencies of Hood and Nowakowski et al. as discussed above. Specifically, Cederholm-Williams is merely cited for teaching the use of glass wool as an activating agent. Cederholm-Williams does not discuss the use of such an agent in combination with a restoration agent and certainly not within a single chamber. Further, there is no motivation in either Hood or Nowakowski et al. to add such an activation agent to their systems and the Office Action provides no citation in any of the references providing such motivation. Additionally, Cederholm-Williams fails to teach the lumen assembly of claim 22. Hence, the pending claims are believed allowable over the combined teaching of these three references.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

Examination and reconsideration of the application as amended is requested. After amending and canceling claims as set forth above, claims 14-17, 19-22 and 24-28 remain pending in the application and are now believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

This amendment results in a total of four (4) independent claims. Please charge the appropriate fee for the addition of one independent claim in excess of the allotted three to Deposit Account No. 13-2546. This amendment also results in a total of 87 dependent claims. Please charge the appropriate fee for the addition of 59 dependent claims to Deposit Account No. 13-2546.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned attorney at 763-391-9661.

Applicant respectfully petitions the Commissioner for Patents to extend the time for response to the Office Action dated March 29, 2004 for one (1) month from June 29, 2004 to July 29, 2004. Please charge the fee provided in:

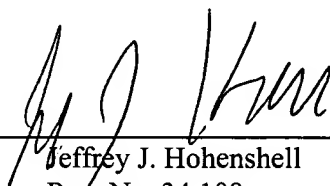
X 37 C.F.R. 1.17(a)(1) Extension for response within first month

to Deposit Account No. 13-2546. Please also charge any additional fees or credit any overpayment to Deposit Account No. 13-2546.

If any additional fee is required in connection with these papers, please charge such fee to Deposit account No. 13-2546.

Date July²⁹, 2004

By



Jeffrey J. Hohenshell
Reg. No. 34,109
Senior Patent Attorney
MEDTRONIC, INC.
MS LC340
710 Medtronic Parkway
Minneapolis, MN 55432
Tel. 763.391.9661
Fax. 763.391.9668